

micronized colistin sulphomethate sodium, optionally together with a carrier, and a container. The container is preferably a capsule.

A3 [0020] Figure 1 shows a particle size analysis of micronized colistin sulphomethate sodium.

In the claims:

Please cancel claims 22, 26, 27 and 28.

Please amend claims 1, 2, 4, 6-13, 15, 18-21, 23, and 25 as follows:

Sub C1
A4 1. Micronized powder particles of colistin sulphomethate sodium wherein at least 90% by volume of the micronized particles have a diameter of from 0.01 to 10 micrometers for use in the treatment of a pulmonary infection by powder inhalation, wherein the colistin sulphomethate sodium is not separated into component form.

2. Colistin sulphomethate sodium for the use as claimed in Claim 1 wherein the micronized powder is mixed with a carrier.

A5 4. A composition comprising micronized colistin sulphomethate sodium as defined in Claim 1 and a carrier, in the absence of free liquid.

6. A composition as claimed in Claim 4 wherein the ratio of colistin sulphomethate sodium to carrier is from 5:1 to 1:2 by weight.

7. A composition as claimed in Claim 4 wherein the ratio of colistin sulphomethate sodium to carrier is from 4:1 to 1:1 by weight.

Sub B1
A6 8. The composition as claimed in Claim 4 wherein at least 50% by volume of the carrier particles have an effective particle size in the range of 30-150 micrometers.

9. A composition as claimed in Claim 4 wherein at least 50% by volume of the micronized colistin sulphomethate sodium has a particle diameter of from 0.01 to 8 micrometers.

10. A composition as claimed in Claim 4 wherein at least 25% of the particles of micronized colistin sulphomethate sodium have a diameter of from 0.01 to 6 micrometers.

11. A composition as claimed in Claim 4 wherein the micronized colistin sulphomethate sodium is prepared in the desired particle size range using a fluid energy mill.

12. A process for the preparation of a composition as claimed in Claim 4 which comprises mixing micronized colistin sulphomethate sodium and a carrier.

13. A pharmaceutical dosage form suitable for use with a dry powder inhaler comprising micronized powdered colistin sulphomethate sodium wherein at least 90% by volume of the particles have a diameter less than 10 micrometers or a composition according to any Claim 4 and a container, said dosage having a content of below 10 wt % water.

15. A capsule containing micronized colistin sulphomethate sodium wherein at least 90% by volume of the micronized powdered particles have a diameter of from 0.01 to 10 micrometers.

18. A capsule as claimed in Claim 15 further comprising a carrier.

19. A capsule as claimed in Claim 15 when the carrier is lactose.

20. A capsule according to Claim 15 which is opaque.

21. A capsule according to Claim 15 packed in an opaque container.

23. A capsule according to Claim 15 which additionally comprises a micronized bronchodilatory drug.

25. A capsule according to Claim 23 which comprises from 50 to 150 milligrams of colistin sulphomethate sodium and from 1 to 250 micrograms of bronchodilatory drug.

Please add new claim 29 as follows:

29. (New) A composition according to Claim 4 packed in an opaque container.

REMARKS

Claims 1-21, 23-25, and 29 are pending. Claims 22, 26, 27 and 28 have been canceled. Claim 29 has been added.

In response to the Office Action dated April 16, 2002, each one of the cited references has been reviewed, and the rejections and objections made to the claims by the Examiner have been considered. Applicants have traversed all rejections and objections regarding all pending claims, and therefore allowance of these claims is earnestly solicited.